UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: COLUMBIA UNIVERSITY PATENT LITIGATION	)	MDL NO. 1592

MEMORANDUM AND ORDER

WOLF, D.J. August 16, 2004

I. SUMMARY

On September 24, 2002, the United States Patent and Trademark Office (the "PTO") issued U.S. Patent No. 6,455,275 (the "'275 patent"). The Trustees of Columbia University in the City of New York ("Columbia") own the '275 patent. The plaintiffs in these five cases are drug companies. They each license a portfolio of patent rights from Columbia, including the '275 patent (the "Axel patents"). The plaintiffs contend that the '275 patent is invalid and unenforceable and, therefore, refuse to pay Columbia royalties under their respective agreements. The plaintiffs filed lawsuits against Columbia in several courts seeking, among other things, declarations that the '275 patent is both invalid and unenforceable. On April 8, 2004, the Judicial Panel on Multidistrict Litigation transferred all cases relating to the '275 patent to this court for coordinated or consolidated pretrial proceedings.

On February 27, 2004, a non-profit organization called the Public Patent Foundation ("PPF") filed a request with the PTO for re-examination of the '275 patent. On May 6, 2004, the PTO granted

this request and commenced re-examination proceedings. On June 10, 2004, Columbia filed a motion to stay all litigation pending the conclusion of the PTO's re-examination and processing of a re-issue application Columbia promised that it would file in the immediate future (the "Motion to Stay"). The plaintiffs unanimously oppose the Motion to Stay.

On June 22, 2004, the court heard oral argument on the Motion to Stay. For the reasons explained in this Memorandum, the Motion to Stay these cases completely is being denied. However, the court has identified the contention that the '275 patent is invalid under the doctrine of non-statutory double patenting as one that should be able to be quickly developed and decided in 2004, either on a motion for summary judgment or at a trial to be conducted in December 2004. Thus, the court has established a schedule for doing so and is otherwise substantially staying this case.

II. FACTS AND PROCEDURAL HISTORY

The court described in detail the genesis of the '275 patent and other patents in its family (the "Axel patents") in a Memorandum and Order recently issued in one of these cases, Biogen Idec MA Inc. v. Trustees of Columbia University, C.A. No. 03-11329-MLW, slip. op. at 4-10 (D. Mass. Aug. 13, 2004). Of particular note is the fact that the '275 patent issued on September 24, 2002, over twenty-two years after its great-great-great-great-great-great-grandparent application (the "'513 application) was filed on

February 25, 1980.

There are now five cases pending in this Multidistrict Litigation. The parties opposing Columbia are: Biogen Idec MA Inc. ("Biogen"), Genzyme Corporation ("Genzyme") and Abbott Bioresearch Center, Inc. ("Abbott") in C.A. No. 03-11329; Wyeth and Genetics Institute LLC in C.A. No. 03-11570; Amgen and Immunex in C.A. No. 04-10740, which originated in the Central District of California; Genentech, Inc. in C.A. No. 04-11546, which originated in the Northern District of California; and Johnson & Johnson in C.A. No. 04-10743, which originated in the Southern District of New York.

As indicated earlier, on February 27, 2004 the PPF filed a request with the PTO for re-examination of the '275 patent[1] and on May 6, 2004, the PTO decided to re-examine the '275 patent. The substantial new question of patentability that prompted this decision is essentially the same non-statutory double patenting argument that the plaintiffs are presenting to the court in this litigation. See Order Granting Request for Ex Parte Reexamination, No. 90/006,953 (PTO May 6, 2004).

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[1]It appears that the President and Executive Director of the Public Patent Foundation was until recently employed by Patterson, Belknap, Webb & Tyler LLP ("PBWT"). PBWT represents Johnson & Johnson in this litigation. However, the attorney from PBWT appearing for Johnson & Johnson states that "J&J and PBWT had no knowledge of PPF's decision to request reexamination of the '275 patent until after the request was filed and publicized by PPF. Neither J&J nor PBWT consented to or authorized the filing of PPF's request." Johnson & Johnson's Opp. to Mot. to Stay at 2. The court finds no evidence that any plaintiff was involved in the request for re-examination.

As described earlier, on June 10, 2004, Columbia filed a motion to stay this case pending re-examination, which the plaintiffs unanimously oppose. In the Motion to Stay, Columbia claimed that it would soon file a request that the PTO re-issue the '275 patent. On June 17 or 18, 2004, Columbia filed its re-issue application. Columbia included portions of that application as exhibits to a declaration submitted in connection with its Reply Memorandum in support of the Motion to Stay. However, before that date, the plaintiffs had no information about the scope of and grounds for the re-issue application. Accordingly, the plaintiffs, which were required to file oppositions to the Motion to Stay by June 16, 2004, were hampered in their ability to respond to the Motion to Stay. Thus, on June 21, 2004 the plaintiffs filed a sur-reply in opposition to the Motion to Stay addressing the contents of the re-issue application.

Columbia's re-issue application is being prosecuted by John P. White and Gary J. Gershik of Cooper & Dunham LLP. White has since 1980 also prosecuted the '275 patent and other Axel patents.

The '275 patent as issued contains 20 claims. The re-issue application seeks to cancel claim 4, amend claims 1 and 6 through 18, and add 17 new claims.

III. ANALYSIS

The parties acknowledge that the court has the "inherent power to manage [its] dockets and stay proceedings, including the

authority to order a stay pending conclusion of a PTO reexamination" and re-issue. Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988). Columbia argues that the court should exercise this power and allow the Motion to Stay in order to prevent duplicative proceedings before the PTO and the court, and to eliminate the risk that the PTO proceedings might moot, limit or alter the issues presented to the court. These arguments are not persuasive. Therefore, the court chooses not to exercise its power in the facts and circumstances of this case.

The courts and the PTO take different approaches to examining the validity of a patent. Id. at 1428. Consequently, the courts and the PTO may properly reach different conclusions on the same evidence. Id. The court may also consider different or additional evidence. Id. at 1427. Perhaps most importantly, the court can consider additional issues such as prosecution laches and inequitable conduct that the PTO either will not or cannot consider. See 37 C.F.R. §1.291(b) ("Protests raising . . . inequitable conduct issues will be entered in the application file, generally without comment."); Manual of Patent Examining Procedure ("MPEP") §1901.06 ("The examiner will not, under any circumstances, treat or discuss those arguments or points directed by . . . 'inequitable conduct.'"); MPEP §2216 ("Questions relating to grounds of rejection other than those based on prior art patents or printed publications should not be included in the request [for re-

examination] and will not be considered by the examiner if included. Examples of such questions that will not be considered are public use, on sale, and fraud."). Judicial proceedings are also far more adversarial than re-examination and re-issue proceedings before the PTO. See MPEP §1901.07 (discussing limited involvement of protestor in re-issue proceedings); 37 C.F.R. §1.550(g) (discussing limited involvement of requester and third parties in re-examination proceedings). Therefore, judicial proceedings have a significant advantage in reaching a correct result.

Columbia argues that "the reissue proceeding also provides an opportunity for the PTO to address plaintiffs' arguments that the '275 patent is unenforceable because of prosecution laches." Columbia's Mem. in Supp. of Mot. to Stay at 12. This is incorrect. In In re Bogese, 303 F.3d 1362, 1367-68 (Fed. Cir. 2002), the Federal Circuit held that the PTO may refuse to grant a patent because of prosecution laches. However, it also re-affirmed the 1975 decision of the Patent and Trademark Office Board of Appeals in Ex Parte Hull, 191 U.S.P.Q. 157 (PTO Bd. Apps. 1975) that required the PTO to give an applicant notice before it could properly order forfeiture of patent rights. Bogese, 303 F.3d at 1368-69. Thus, although the PTO could put Columbia on notice that future dilatory prosecution during the re-issue application might result in forfeiture and, if Columbia ignored the warning, refuse

to re-issue the patent, it does not appear that the PTO could properly revoke the '275 patent based on any dilatory conduct that has already occurred.

Perhaps more importantly, a complete inquiry into possible prosecution laches will be difficult without the ability to compel the testimony, subject to cross-examination, of John P. White about the delays in the prosecution of the '275 patent. Columbia does not suggest that the PTO has this power.

There are some factors in this case that favor a stay. The cases are at an early stage. Proceedings before the PTO tend to be significantly less expensive than litigation. Resolution of the PTO proceedings could simplify some of the issues that the court must decide or change the issues by altering the language of the claims in the '275 patent.

However, these factors are outweighed by countervailing considerations. Re-examination proceedings are not fully open to the public or truly adversarial. Indeed, Chapter 2200 of the Manual of Patent Examining Procedure is captioned, in part, "Ex Parte Reexamination of Patents." The plaintiffs have no right to be heard unless they file their own requests for re-examination, which could generate more delay. The plaintiffs' limited rights to protest re-issue under Chapter 1900 of the MPEP are not an adequate substitute for proceedings before this court. As protesters, the plaintiffs would not be fully informed of all aspects of the

proceedings, such as interviews between White and the examiner, or have a right to appeal adverse decisions. Nor, as discussed earlier, would the plaintiffs be able to present their claims of prosecution laches or inequitable conduct to the PTO.

The average re-examination takes 21 months. See Norton Decl. Ex. E. However, the PTO will not cancel claims until after the time for appeal has expired and any appeals have terminated. See 35 U.S.C. §307. Thus, if Columbia is dissatisfied with the results of the proceedings, the process may take significantly longer as Columbia appeals to the Board of Patent Appeals and Interferences and then to the Court of Appeals for the Federal Circuit. The parties offer no statistics as to the typical length of a re-issue proceeding. However, if the court stays these cases pending the outcome of the PTO proceedings, the PTO will treat the re-issue application with special priority. In spite of this treatment, however, Columbia will retain significant influence over the length of re-issue proceedings. This case, on the other hand, can proceed significantly faster because the court intends to focus first on the non-statutory double patenting claims raised by the plaintiffs and has established a schedule for the resolution of those claims, on a motion for summary judgment or by trial, in 2004. See June 23, 2004 Order (Docket No. 32).

A stay would significantly harm the plaintiffs. While any stay is in effect, the drug companies' potential damages will

mount. The uncertainty over whether they owe Columbia royalties on their products might create difficulties in pricing those products. It may also cause the drug companies to delay introduction of new products or needlessly invest money in efforts to design around an invalid patent. Such efforts are likely to be extremely costly in a highly regulated industry such as the one in which the drug companies compete because changes in their product designs or manufacturing processes may require regulatory approval.

Eliminating this uncertainty is the very reason that the plaintiffs brought these declaratory judgment actions. It is also the reason that Congress and the President created a declaratory judgment remedy. See 28 U.S.C. §2201.[2]

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[2]The importance of eliminating uncertainty regarding the scope and validity of patents was also one of the driving forces behind the formation of the Court of Appeals for the Federal Circuit.

> The Reagan Administration did strongly support the creation of the Federal Circuit based, among other things, upon the recommendation of then-Secretary of Commerce, the late Malcolm Baldridge. Having served as the very successful Chief Executive of Scovill Industries, Secretary Baldridge often expressed the view that successful business executives are able to "manage around" adversity; they cannot handle uncertainty. And as the several federal circuits drifted farther and farther apart in their interpretations of key sections of the patent code, the inevitable uncertainty actually called into question the viability of an effective U.S. patent system for protecting new technology.

Hon. Gerald J. Mossinghoff, Statement Before the Federal Trade Commission and Department of Justice Hearings on Competition & Intellectual Property Law and Policy in the Knowledge-Based Economy 6 (Feb. 6, 2002), available at http://www.ftc.gov/os/comments/intelpropertycomments/mossinghoffgeraldj.pdf.

A stay would also have the effect, if not the purpose, of causing delay in a case which involves, in part, the assertion that the '275 patent is unenforceable under the doctrine of prosecution laches because of the twenty-two year delay in prosecution that has already taken place. See Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found., 277 F.3d 1361 (Fed. Cir. 2002); In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002). Now, over twenty-four years after he first filed the '513 application, John P. White, on behalf of Columbia, is telling the PTO that the patent should be re-issued because the issued claims are not broad enough. If the claims of the '275 patent are invalid as issued, the broader claims may be invalid as well. In denying the motion of Biogen and Genzyme to preliminarily enjoin termination of their license agreements, this court found that they have shown that they are likely to prevail in proving that if the '275 patent is valid, it is unenforceable because of prosecution laches. See Biogen Idec MA Inc., supra, slip op. at 21-23. This finding militates against granting the complete stay of this case that Columbia seeks.

In any event, if, as threatened, Columbia counterclaims against the plaintiffs for allegedly infringing activities that occur before the '275 patent is re-issued, the court will still have to construe the original claims in order to determine if the scope of the claims is identical. See Bloom Eng'g Co. v. N. Am. Mf'g Co., 129 F.3d 1247, 1250 (Fed. Cir. 1997). "Unless a claim

granted or confirmed upon reexamination is identical to an original claim, the patent can not be enforced against infringing activity that occurred before issuance of the reexamination certificate." Id. Columbia has not disclaimed its intent to pursue such claims, nor has it argued that the preliminary amendments it submitted as part of its re-issue application would prevent it from doing so. Therefore, Columbia's argument that "[g]iven that claim interpretation will play a central role in this litigation, it makes no sense to proceed with these . . . related actions when it is entirely possible that some or all of the claims of the '275 patent may be amended as a result of reexamination or reissue" is diminished in force. Columbia's Mem. in Supp. of Mot. to Stay at 10; accord Columbia's Reply at 5-6.

In view of the foregoing, Columbia's request that this Multidistrict Litigation be stayed completely is being denied.

However, as indicated earlier, at the June 22, 2004 hearing the court identified the contention that the '275 patent is invalid under the doctrine of non-statutory double patenting as one that should be able to be quickly developed and decided in 2004, either on a motion for summary judgment or at a trial to be conducted in December 2004. See Geneva Pharms., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373, 1377-78 (Fed. Cir. 2003); Biogen Idec MA Inc., supra, slip op. at 16, 18-21. Therefore, the court established a schedule for the resolution of the non-statutory double patenting

issue in 2004, and otherwise substantially stayed the remainder of this case to permit the parties to focus on that issue, which may, as a practical matter, end these cases.[3] See June 23, 2004 Order (Docket No. 32).

IV. ORDER

Accordingly, it is hereby ORDERED that Columbia's Motion to Stay Litigation Pending Outcome of Reexamination and Reissue Proceedings in the Patent and Trademark Office (Docket No. 6) is DENIED.

/s/ Mark L. Wolf
UNITED STATES DISTRICT JUDGE

[3]The court may permit the depositions of certain elderly witnesses to be taken in order to preserve their testimony on all issues in the event that a decision of the non-statutory double patenting question does not resolve these cases. See June 23, 2004 Order ¶3.